EXHIBIT A

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Court of Common Pleas

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Confirmation Nbr. 2556263

CHARLES YERKEY, ET AL.

vs.

SORIN GROUP DEUTSCHLAND, ET AL.

CV 22 963729

Judge: MICHAEL J. RUSSO

Pages Filed: 41

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

CHARLES YERKEY 1525 Osage Avenue Akron, Ohio 44305 and MELODY YERKEY 1525 Osage Avenue Akron, Ohio 44305 Plaintiffs SORIN GROUP DEUTSCHLAND, GmbH Linderghstrasse 25 D-80939 München Germany and SORIN GROUP USA, INC. 14401 West 65th Way Arvada, Colorado 80004 and SORIN CRM USA, INC. 14401 West 65th Way Arvada. Colorado 80004 and CLEVELAND CLINIC FOUNDATION c/o CT Corporation Systems, Statutory Agent 4400 Easton Way Suite 125 Columbus, Ohio 43219 and	CASE NO. JUDGE **COMPLAINT** **Affidavit of Merit Attached** [***Jury Demand Endorsed Hereon***]

CLEVELAND CLINIC FOUNDATION)
d/b/a CLEVELAND CLINIC)
9500 Euclid Avenue)
Cleveland, OH 44195)
)
and)
)
CLEVELAND CLINIC – MAIN CAMPUS)
9500 Euclid Avenue)
Cleveland, OH 44195)
)
Defendants)
)

Now comes Plaintiffs, Charles Yerkey and Melody Yerkey, husband and wife, by and through their undersigned counsel and for their Complaint states and avers as follows:

PARTIES, JURISDICTION & VENUE

1. Plaintiffs, Charles Yerkey and Melody Yerkey, husband and wife, are citizens of the State of Ohio, residing therein at 1525 Osage Ave, Akron, OH 44305.

2. Defendant, Sorin Group Deutschland GmbH ("Sorin Deutschland"), is a foreign for- profit corporation headquartered in Munich, Germany and is a wholly owned subsidiary of LivaNova, PLC. Upon information and belief, Sorin Deutschland designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin heating and cooling device ("HCD") that was used during Charles Yerkey's heart surgery, hereinafter described.

3. Defendant, Sorin Group USA, Inc. ("Sorin USA"), is a Delaware Corporation and wholly owned subsidiary of LivaNova, with a principal place of business at 14401 West 65th Way, Arvada, Colorado 80004. Upon information and belief, Sorin USA designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin HCD used in the surgery of Charles Yerkey's heart surgery.

4. Defendant, Sorin CRM USA, Inc. (Sorin CRM"), is a Colorado Corporation and wholly owned subsidiary of LivaNova, with a principal place of business at 14401 West 65th Way, Arvada, Colorado 80004. Upon information and belief, Sorin CRM designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin HCD used in the surgery of Charles Yerkey's heart surgery.

5. Personal jurisdiction exists over Defendant, Sorin Deutschland, due to the fact that it regularly conducted business in Ohio during all relevant times, including the marketing, sale, and/or distribution of the Sorin HCD. Sorin Deutschland maintained and continues to maintain general and specific contacts in Ohio.

6. Personal jurisdiction exists over Defendant, Sorin USA, due to the fact that it regularly conducted business in Ohio during all relevant times, including the marketing, sale, and/or distribution of the Sorin HCD. Sorin USA maintained and continues to maintain general and specific contacts in Ohio. Upon information and belief, Sorin USA sold the Sorin HCD directly to Defendant, Cleveland Clinic – Main Campus.

7. Personal jurisdiction exists over Defendant, Sorin CRM, due to the fact that it regularly conducted business in Ohio during all relevant times, including the marketing, sale, and/or distribution of the Sorin HCD. Sorin CRM maintained and continues to maintain general and specific contacts in Ohio. Upon information and belief, Sorin CRM sold the Sorin HCD directly to Defendant, Cleveland Clinic – Main Campus. Sorin CRM expressly consented to jurisdiction in Ohio by registering as a foreign corporation doing business in the State.

8. Hereinafter, Defendants, Sorin Deutschland, Sorin USA and Sorin CRM,

shall be collectively referred to as the "Sorin Defendants."

9. At all relevant times, the Sorin Defendants were acting individually, and/or by and through their duly authorized actual, apparent, and/or ostensible agents, servants, and/or employees, who were acting within the scope of their employment, service, and/or agency with the Sorin Defendants. The identities of these authorized, actual, and/or ostensible agents, servants, and/or employees, are known to the Sorin Defendants and are currently unknown to Plaintiffs, and include, but are not limited to, all those responsible for the design, development, testing, assembling, manufacturing, marketing, sale, and/or distribution of the Sorin HCD and those responsible for the collection, dissemination, and communication of information relating to the safety of the Sorin HCD. Sorin Defendants are therefore liable to Plaintiffs for the negligent acts and omissions of the aforementioned agents.

10. During all relevant times, the Sorin Defendants designed, manufactured, assembled, marketed, sold, and/or distributed the Sorin HCD that is the subject of this lawsuit and that was used during Charles Yerkey's heart surgery at Cleveland Clinic – Main Campus in Cleveland, OH on or about May 15, 2017.

11. At all relevant times, Sorin Defendants knew, or should have known, that the design and/or manufacturing defects in its Sorin HCD allowed bacterial colonization to which patients like Charles Yerkey would be, and were in fact, exposed to during heart surgery, thus posing a significant risk of bodily injury.

12. Defendant, Cleveland Clinic Foundation, is a non-profit business corporation entity organized and existing under the laws of the State of Ohio and owns, operates, controls and/or maintains a network of hospitals, medical practices, clinics and physicians, including Cleveland Clinic – Main Campus, and employs and/or oversees physicians, nurses, and staff

who clean and maintain Sorin HCD machines.

13. Defendant, Cleveland Clinic Foundation d/b/a Cleveland Clinic, is a non-profit business entity organized and existing under the laws of the State of Ohio and owns, operates, controls and/or maintains a network of hospitals, medical practices, clinics and physicians, including Cleveland Clinic – Main Campus, and employs and/or oversees physicians, nurses, and staff who clean and maintain Sorin HCD machines.

14. Defendant, Cleveland Clinic – Main Campus, is a nonprofit business corporation entity organized and existing under the laws of the State of Ohio, with a principal place of business at 9500 Euclid Avenue Cleveland, OH 44195. Plaintiff is asserting a claim against this Defendant for its negligence and the negligence of its agents, employees, and/or servants. However, this is not a medical claim pursuant to ORC 2305.113, thus no affidavit of merit is required under Civil Rule 10(D)(2).

15. Hereinafter, Defendants, Cleveland Clinic Foundation, Cleveland Clinic Foundation d/b/a Cleveland Clinic and Cleveland Clinic – Main Campus, shall be collectively referred to as the "Cleveland Clinic Defendants."

16. Venue is proper in Cuyahoga County because the conduct that is the subject of these claims was completed by the Cleveland Clinic Defendants in Cuyahoga County, and because Sorin Defendants regularly conduct business in Cuyahoga County and marketed, distributed and/or sold the Sorin HCD used in the surgery of Charles Yerkey in Cuyahoga County.

17. At all relevant times, the Cleveland Clinic Defendants were acting individually, and/or by and through their duly authorized actual, apparent, and/or ostensible agents, servants, and/or employees, who were acting within the course and scope of their

employment, service, and/or agency with the Cleveland Clinic Defendants. The identities of these authorized, actual, and/or ostensible agents, servants, and/or employees, are known to Cleveland Clinic Defendants, and currently unknown to Plaintiffs, and include, but are not limited to, any and all administrators, perfusionists, operating room technicians, staff personnel, and/or other agents who were responsible for: (1) the maintenance, inspection, cleaning, and/or disinfection of the Sorin HCD used during the heart surgery of Charles Yerkey on May 15, 2017; (2) the adoption, enforcement, and/or execution of policies and procedures for the maintenance, inspection, cleaning, and/or disinfection of the Sorin HCD on or before May 15, 2017; and (3) the receipt, dissemination, and/or communication of information concerning the Sorin HCD and the risks such devices posed to patients. The Cleveland Clinic Defendants are therefore liable to Plaintiffs for the negligent acts and omissions of its agents.

18. At all relevant times, Cleveland Clinic Defendants, and/or their agents, were required to use reasonably safe and accepted standards of cleaning, maintaining, and using the Sorin HCD.

19. At all relevant times, Plaintiff, Charles Yerkey, was under the care of Cleveland Clinic Defendants directly and through its agents, ostensible agents, employees, and staff.

FACTS

20. At all material times, the Sorin Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, delivering, and/or introducing their Sorin HCD into the stream of commerce, including Cleveland, Ohio.

21. At all material times, the Sorin HCD was used during open heart surgery at the Cleveland Clinic – Main Campus, and specifically during the aortic valve replacement #25 Carpentier-Edwards pericardial valve; ascending aorta with a #32 Gelweave graft performed upon Charles Yerkey on May 15, 2017.

22. The Sorin HCD is a free-standing unit on wheels, separate from the heart-lung machine, that consists of cold and hot reservoirs of water that are circulated to and from the heart lung machine via long plastic tubes or hoses that are connected to the heat exchanger of the heart and lung machine. At no time does the HCD or the water circulating to and from the HCD come in direct contact with the patient or the patient's blood.

23. On or about April 11, 2011 through April 13, 2011, the Federal Drug Administration ("FDA") conducted an inspection of the Sorin Group Deutschland GmbH manufacturing facility where, upon information and belief, the Sorin HCD in question was manufactured, and filed an Establishment Inspection Report that found deviations to the quality system regulations that included the following observation that the Sorin Defendants had not adequately implemented the procedure for design controls in relation to the Heater-Cooler 3T design file. Specifically, the FDA noted that:

a. The design inputs do not include the requirement for cleaning of the water tank.

b. The design output of the device includes a cleaning procedure for the US; however, the cleaning agents to be used are not available in the US.

c. The design verification was not performed in relation to the US cleaning instructions for uses.

d. Risk analysis does not include possible contamination from water held in the tank in relation to the patient, operating room, or operation.

e. Design Changes were not adequately verified.

24. The Sorin Defendants knew, or should have known, based on their own

information, investigation, and/or testing, and based on an outbreak of cases in Europe reported in medical literature as early as 2011, of the association of non-tuberculous mycobacterium ("NTM") infections with the use of their Sorin HCD when used in heart surgery.

25. Upon information and belief, in September of 2013, the Sorin Defendants were specifically notified by a team of infectious disease physicians and epidemiologists at Zurich University Hospital in Switzerland that testing had confirmed that Sorin HCD's were contaminated with mycobacterium chimaera and that the devices were spraying the bacterium into the air of operating rooms causing patient infections.

26. Upon information and belief, in January 2014 the Sorin Defendants were again notified by physicians at Zurich University Hospital that Sorin HCD's were releasing water vapor during surgery that was contaminated with mycobacterium and that the airborne bacterium was being transmitted to and infecting patients.

27. Upon information and belief, the Sorin Defendants took no action to warn hospitals and/or purchasers of Sorin HCD units that the units were contaminated and causing infections until June 2015 and in fact engaged in a scheme to suppress this information from hospitals in the United States.

28. In June of 2015, the Sorin Defendants were forced to finally acknowledge that 3T HCUs were contaminated with biofilm and causing airborne infections with *m. chimaera* because the physicians and epidemiologists at Zurich University Hospital published a peer-reviewed paper (Prolonged Outbreak of Mycobacterium chimaera Infection After Open Heart Surgery) proving that the 3T was the cause of never-before-seen outbreak of *m. chimaera* in patients undergoing cardio-thoracic surgery.

29. In August 2014, prior to publication of the Prolonged Outbreak paper, Sorin

discovered that the water supply at its Sorin Deutschland manufacturing facility was contaminated with NTM. It also discovered it had been filling its devices with this contaminated water during production for years. Sorin did not tell hospitals or health care providers about this discovery and indeed, this information was not made public until the FDA issued a "Safety Communication" on June 1, 2016.

30. On or about August 24, 2015 through August 27, 2015, the FDA performed an inspection of the Sorin Deutschland's manufacturing facility as a follow-up to its April 2011 inspection and noted several objectionable observations related to the lack of validation for an implemented disinfection process related to the Sorin Heater Cooler System 3T, the same or similar problem identified at the 2011 inspection.

31. The Sorin Defendants knew, or should have known, based on their own information, investigation and/or testing, based on reports received in January 2014, and based on an outbreak of NTM infections in Europe, that there was a risk of NTM infections when its Sorin HCD was used during heart surgery.

32. Despite knowledge of the design defect and NTM contamination during the manufacture of its Sorin HCD, and despite knowledge of the catastrophic injuries, conditions, complications, infections, and/or deaths caused by the use of its Sorin HCD during heart surgery, the Sorin Defendants continued to manufacture, market, advertise, sell, and/or deliver its Sorin HCD to hospitals throughout the United States, including to Cleveland Clinic – Main Campus in Cleveland, Ohio.

33. Sorin Defendants knew, or should have known, prior to Charles Yerkey's heart surgery on May 15, 2017, that using the Sorin HCD posed serious risks to the health and lives of patients undergoing surgery, particularly heart surgery. Despite this, Sorin

Defendants failed to take action or warn against these dangers.

34. On May 15, 2017, Mr. Yerkey underwent heart surgery to repair severe bicuspid aortic stenosis and a dilated ascending aorta performed by Nicholas Smedira, M.D. at Cleveland Clinic – Main Campus.

35. Upon information and belief, Sorin HCD, Serial Number 16511433 was utilized during Mr. Yerkey's May 15, 2017 heart surgery.

36. Upon information and belief, the above particular Sorin HCD unit was in service at Cleveland Clinic from October of 2008 to January of 2018.

37. The operative report for the May 15, 2017 heart surgery documents that there were no intraoperative complications.

38. In July of 2019, Mr. Yerkey began experiencing intermittent cold symptoms, including weakness, malaise, cold chills, shaking, night sweats, poor appetite, and fevers.

39. On July 26, 2019, Mr. Yerkey presented to his primary care provider with the aforementioned symptoms; he was suspected of having prostatitis and was prescribed oral doxycycline.

40. In early August of 2019, Mr. Yerkey was hospitalized with fevers, shakes, chills, weakness, fatigue, and general malaise, poor appetite, and night sweats; he was further noted to be suffering from a low white blood count and anemia, and was advised that he should undergo bone marrow testing.

41. On August 12, 2019, Mr. Yerkey underwent bone marrow testing and lab work, including blood cultures; at that time, the bone marrow testing was nondiagnostic and

his blood cultures were negative for infection.

42. On August 21, 2019, Mr. Yerkey was admitted to Akron General Hospital for further workup for suspected infective endocarditis due to persistent high fever and leukopenia; he was also suffering from weight loss.

43. On August 30, 2019, Mr. Yerkey was transferred from Akron General Hospital to Cleveland Clinic – Main Campus; he underwent transthoracic echocardiogram ("TEE") which reported "no valvular vegetation seen."

44. On August 31, 2019, Bo Xu, M.D. documented that Mr. Yerkey had, over the past two weeks, developed splinter hemorrhages in his left thumb fingernail and that prosthetic aortic valve endocarditis could not be excluded. At that time, Dr. Xu made the following recommendations: dynamic 4D endocarditis protocol CT imaging, infectious disease consultation, and hematology consultation regarding ongoing leukopenia.

45. On September 2, 2019, Mr. Yerkey underwent CT imaging of the chest, which reported abnormal soft tissue thickening along the posterior of the aortic root, as well as focal areas of outpouching along the posterior aortic root, indicative of infection.

46. On September 9, 2019, an additional bone marrow biopsy was performed which, *reported on September 23*, demonstrated granulomatous infiltration of the bone marrow with pancytopenia and bone-marrow infection secondary to disseminated mycobacterium.

47. On September 16, 2019, Mr. Yerkey underwent redo sternotomy, aortic valve replacement/root/ascending aorta replacement with 25 mm homograft, reimplantation of the coronary arteries, and tricuspid valve repair with 32 mm CE classic ring. The explanted aortic valve was sent for pathologic evaluation and diagnosis.

48. On September 23, 2019, Mr. Yerkey was discharged to home on antimycobacterial medications.

49. On September 24, 2019, the pathology results confirmed that the explanted aortic valve was positive for mycobacterium infection.

50. The records demonstrate that the Cleveland Clinic – Main Campus, sent the bacterial isolate of mycobacterium to National Jewish Health for additional testing who confirmed the infective organism was *m. chimaera*.

51. Mr. Yerkey was immediately placed on a cocktail of powerful antibiotics known to have significant side-effects including amikacin, azithromycin, and rifampin, among other potent medications.

52. On September 27, 2019, Mr. Yerkey underwent bilateral eye examinations which revealed he was suffering from retinal and choroidal lesions in both eyes, as well as disseminated chorioretinitis of both eyes; additional documentation indicates that the subretinal lesions were caused by *m. chimaera*.

53. On October 1, 2019, Mr. Yerkey was again admitted to the Cleveland Clinic – Main Campus with fatigue, tachycardia, shortness of breath, and an erythematous popular rash on his extremities and trunk. Further noted was that "patient feeling depressed over hospital stay, he wants a psych consult (ordered), healing services for pastoral support, pet therapy, and PT consult for deconditioning." Also documented was that Mr. Yerkey would be required to remain on amikacin, azithromycin, and rifampin for, at least, one year per infectious disease.

54. On October 25, 2019, Mr. Yerkey was discharged to home on community parenteral antibiotic therapy for the *m. chimaera* infection.

55. On November 6, 2019, Mr. Yerkey underwent further evaluation at the Cleveland Clinic Heart and Vascular Institute where it was documented that he was suffering from "mycobacterium chimaera infection associated with extracorporeal equipment."

56. Mr. Yerkey's *m. chimaera* infection has resulted in permanent and significant injuries, including, but not limited to, disseminated and chronic mycobacterium infection requiring long-term use of toxic antibiotics, multi-organ system injuries secondary to disseminated *m. chimaera* infection, bone marrow infection, persistent and active *m. chimaera* infection in his eyes, multiple lung nodules, leukocytopenia, atelectasis, fluid overload, permanent kidney injury, and emotional distress/harm.

57. On June 15, 2015, Sorin Defendants issued a safety notice to hospitals that purchased a Sorin HCD again advising them of the potential for infection and instructions for cleaning and disinfecting the Sorin HCD.

58. Upon information and belief, the original Sorin HCD cleaning and disinfecting process involved six steps. The updated process, posted on Sorin's website, included fifty-six steps to "enhance" the cleaning and disinfecting process.

59. Upon information and belief, the "enhanced" cleaning process developed by Sorin Defendants was never validated and subsequent studies showed it was ineffective at removing mycobacterium biofilm.

60. On July 15, 2015, the FDA issued a Class 2 Recall of the Sorin 3T Heater-Cooler due to the "[p]otential colonization of ... Mycobacteria, in Sorin Heater-Cooler devices."

61. On or about September 18, 2015, the FDA received a MAUDE Adverse Event Report from a health care provider that found an unusual cluster of NTM in patients

after cardiothoracic surgery. Additionally, the health care provider expressed concern about inconsistent cleaning and disinfecting instructions for the Sorin HCD.

62. On October 15, 2015, the FDA issued a Safety Communication explaining that the Agency received thirty-two Medical Device Reports of infections associated with heater-cooler device contamination.

63. On October 21, 2015, The Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance Communication to raise awareness about the relationship between NTM infections and heater-coolers.

64. On December 11, 2015, the Pennsylvania Department of Health ("PADOH") issued an advisory warning that the Sorin HCD had the potential for colonization and aerosolization of bacteria.

65. The PADOH noted the inconsistencies in cleaning and disinfecting instructions from heater-cooler manufacturers, including the Sorin Defendants.

66. Additionally, the PADOH stated it "observed engineering differences that might predispose certain units to increased risk of biofilm and aerosolization of bacteria."

67. A public health investigation of heater-cooler devices in Switzerland found air culture samples that were positive for NTM.

68. On December 29, 2015, the FDA issued a warning letter to LivaNova's CEO identifying several "serious" violations of the Federal Food, Drug, and Cosmetic Act ("the Act") regarding the Sorin HCD, including the following:

a. The devices were "adulterated" within the meaning of section 501(h) of the Act in that "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21,

Code of Federal Regulations (CFR), Part 280;"

b. Failure to establish and maintain procedures for the identification, documentation, validation, or, where appropriate, verification, review and approval of design changes before their implementation, as required by 21 CFR 820.30(i);

c. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a);

d. Failure to adequately develop, implement, and maintain written Medical Device Reporting ("MDR") procedures, as required by 21 CFR 803.171;

e. Failure to submit to the FDA an approved application for premarket approval (PMA) in effect pursuant to section 5159(a) of the Act or an approved application for an investigational device exemption under section 520(g) of the Act;

f. Failure to notify the FDA of the intent to introduce the device into commercial distribution as required by section 510(k) of the Act, resulting in misbranding of the Heater Cooler System 3T as defined by section 520(o) of the Act;

g. Failure to submit to the FDA a new 510(k), to assure that the appropriate testing and validation of the cleaning/disinfecting protocols had taken place, following significant labeling changes that can affect the safety or effectiveness of the device, specifically, distributing the Sorin HCD with Modified Instructions for Use (Versions 013 and 014) with respect to the operating, maintaining, cleaning, and disinfecting of the device, including adding more instruction details, changes to the cleaning/disinfecting process (e.g. chemicals used and amounts used), and expansion of the process to include the entire circuit instead of only the tanks;

h. Failure or refusal to furnish material or information, with respect to the device in question, to the FDA as required by or under section 519 of the Act and 21 CFR Part 806-Medical Devices; Reports of Corrections and Removals, resulting in **"misbranding"** of the Sorin 3T Heater Cooler System device as defined in section 502(t)(2) of the Act; and,

i. Failure to submit to the FDA a written report, as required by 21 CFR 806.10, of any correction or removal of advice initiated to remedy a violation of the Act caused by the device which may present a risk to health.

69. On June 1, 2016, the FDA issued a "Safety Communication" warning patients

who had undergone surgery in which a Sorin HCD was used that NTM contamination was found on the production line and in the water supply at the Sorin Deutschland's manufacturing facility.

70. At all relevant times, the Sorin Defendants marketed its Sorin HCD to the medical community, including to the Cleveland Clinic defendants and their servants, agents and employees who were involved in the purchase and maintenance of the of the Sorin HCD used during Charles Yerkey's heart surgery in May 2017, as a safe, effective, reliable medical device to be used during heart surgery, such as the one performed on Charles Yerkey.

71. At all relevant times, the Sorin Defendants marketed and sold their Sorin HCD to the medical community, including the Cleveland Clinic defendants, hospitals, administrators, cardiothoracic surgeons, perfusionists, and/or other consumers when it knew, or should have known, of a serious design defect that exposed heart surgery patients to NTM, a potentially life-threatening infection.

72. At all relevant times, the Sorin Defendants failed to adequately test or research the risks and benefits of its Sorin HCD.

73. At all relevant times, feasible and alternative designs and products to the Sorin HCD have existed. Indeed, upon information and belief, the Sorin Defendants initiated design and manufacturing changes to the Sorin HCD beginning in 2015.

74. At all relevant times, the Sorin HCD was used during heart surgery procedures, a manner foreseeable by Sorin Defendants.

75. At all relevant times, the Sorin Defendants provided incomplete, ineffective, inadequate, and misleading instructions and training to the users of its Sorin HCD, including

the Cleveland Clinic defendants and their agents and employees who were involved in the purchase, maintenance and use of the of the Sorin HCD used during Charles Yerkey's heart surgery in May 2017.

76. At all relevant times, the Sorin HCD used in the heart surgery of Charles Yerkey was in the same or substantially similar condition as when it left the possession of the Sorin Defendants.

77. Charles Yerkey contracted a disseminated NTM infection from a contaminated Sorin HCD during his heart surgery at Cleveland Clinic – Main Campus in May 2017.

78. The Cleveland Clinic Defendants and their agents who were involved in the purchase, maintenance and use of the Sorin HCD used during Charles Yerkey's heart surgery in May 2017, undertook and/or assumed a duty to use clean and contaminant-free equipment, to avoid harm to him. The Cleveland Clinic defendants breached that duty.

79. Charles Yerkey relied on the knowledge, treatment, skill, and expertise, of the Cleveland Clinic defendants and their agents who were involved in the purchase, maintenance and use of the Sorin HCD used during Charles Yerkey's heart surgery in May 2017.

80. Upon information and belief, The Cleveland Clinic defendants failed to follow the cleaning instructions that came with the Sorin 3T, thus allowing pervasive *m. chimaera* biofilm to form and increasing the amount of *m. chimaera* aerosolized into the operating room during cardiac surgery.

81. The conduct of all Defendants increased the risk of harm for, was a substantial factor in causing, and/or was a factual cause of, the injuries and damages suffered

by Charles Yerkey.

82. As a direct and proximate result of the actual malice, conscious disregard, wanton, reckless, outrageous, tortious, and/or negligent conduct of all Defendants, jointly and severally, Charles Yerkey experienced multiple injuries and damages, including, but not limited to: disseminated and chronic mycobacterium infection requiring long-term use of toxic antibiotics, multi-organ system injuries secondary to disseminated *m. chimaera* infection, bone marrow infection, persistent and active mycobacterium infection in his eyes, multiple lung nodules, leukocytopenia, atelectasis, fluid overload, permanent kidney injury, and emotional distress/harm. These injuries have left him disabled, unable to perform his avocation, and have caused substantial pain, suffering, and loss of life's pleasures.

83. Plaintiffs claim all damages recoverable under the law, including compensatory and punitive damages (punitive damages against the Sorin Defendants only).

COUNT I
OHIO PRODUCTS LIABILITY CLAIM ORC 2307.75
STRICT LIABILITY-DEFECTIVE DESIGN

Plaintiffs v. Sorin Defendants

84. The preceding paragraphs are incorporated by reference as though fully set forth herein.

85. Sorin Defendants are the manufacturer of the Sorin HCD, as that term is defined in ORC 2307.71(A)(9).

86. Alternatively, Sorin Defendants are suppliers of the Sorin HCD, as that term is defined by ORC 2307.71(A)(15) and ORC 2307.78.

87. At all relevant times, the Sorin Defendants were engaged in the business,

design, development, testing, promotion, manufacture, assembly, and/or sale of the Sorin HCD used in the heart surgery of Charles Yerkey at Cleveland Clinic – Main Campus on or about May 15, 2017.

88. The Sorin HCD was defective at the time it was designed, manufactured, assembled, and sold by the Sorin Defendants in that its defective design prevented it from being reliably and consistently cleaned, disinfected, and maintained based on the expected and reasonably foreseeable use of the Sorin HCD with its accompanying instructions, thus rendering the Sorin HCD unsafe for use by the defendant hospital for the use for which it was intended, namely the heart surgery of Charles Yerkey, the ultimate user, on May 15, 2017.

89. The Sorin HCD used by the Cleveland Clinic Defendants for the heart surgery of Charles Yerkey, on May 15, 2017, was expected to reach, and did reach, the intended consumer, Cleveland Clinic Defendants, without substantial relevant change in the condition in which it was sold by the Sorin Defendants.

90. At the time the Sorin HCD left the possession and control of the Sorin Defendants it was in a defective condition, unreasonably dangerous to Charles Yerkey, and others, in that it was contaminated with ***m. chimaera*** during production and designed in a manner that permitted the bacteria to collect, grow, and/or flourish, and subsequently to come in direct contact with and be aerosolized to contaminate the surrounding area in the operating room suite during heart surgery.

91. At all relevant times, the Sorin Defendants intended its Sorin HCD to be used during heart surgery cases, and knew or should have known that it would have been used in patients like Charles Yerkey, who underwent heart surgery at Cleveland Clinic – Main Campus.

92. At all relevant times, the use of the Sorin HCD during heart surgeries, such as in patients like Charles Yerkey, was reasonably foreseeable to the Sorin Defendants as its Sorin HCD was used in the manner for which it was intended by the Cleveland Clinic Defendants who purchased and used the Sorin HCD for the ultimate consumer, Charles Yerkey.

93. At all relevant times, Charles Yerkey could not have, by the exercise of reasonable care, discovered the design defects and risks as noted herein, nor could he have been expected to perceive the danger, and thus the unreasonably dangerous and hazardous condition of the Sorin HCD was unknowable to Charles Yerkey.

94. At all relevant times, the Sorin HCD used during the heart surgery of Charles Yerkey at Cleveland Clinic – Main Campus on May 15, 2017, was defectively designed, rendering it defective and unreasonably dangerous and hazardous when it left the possession of the Sorin Defendants.

95. At all relevant times, the Sorin HCD designed, manufactured, marketed, sold, and/or placed in the interstate stream of commerce in the United States by the Sorin Defendants was inherently and unreasonably dangerous and defective, and was unfit and unsafe for its intended and/or reasonably foreseeable uses, and did not meet and/or perform to the expectations of consumers like Charles Yerkey, and his health care providers, including the Cleveland Clinic Defendants.

96. At all relevant times, Charles Yerkey was the ultimate consumer of the defective Sorin HCD used during his heart surgery at Cleveland Clinic – Main Campus on May 15, 2017.

97. At all relevant times, Charles Yerkey had the reasonable expectation that

the Sorin HCD would not be unreasonably dangerous and defective and would increase his risk of contracting a life-threatening NTM infection.

98. At all relevant times, the design defect of the Sorin HCD created a potentially catastrophic and/or life-threatening risk to patients like Charles Yerkey that far outweighed its utility and far outweighed the cost of designing, manufacturing, and producing an alternate design that was not defective.

99. The use of the Sorin HCD was a factual cause of the injuries and damages sustained by Charles Yerkey.

100. As a direct and proximate result of the use of the defective Sorin HCD, Charles Yerkey was catastrophically injured and sustained severe pain, suffering, disability and also incurred expenses for medical care and treatment.

101. By reason of its designing, manufacturing, assembling, and distributing the Sorin HCD in a defective and unreasonably dangerous condition, the Sorin Defendants are strictly liable to Plaintiffs for Charles Yerkey's injuries and damages and Melody Yerkey's loss of consortium.

COUNT II
OHIO PRODUCTS LIABILITY CLAIM ORC 2307.74 STRICT LIABILITY-DEFECTIVE MANUFACTURE

Plaintiffs v. Sorin Defendants

102. The preceding paragraphs are incorporated by reference as though fully set forth herein.

103. Sorin Defendants are the manufacturer of the Sorin HCD, as that term is defined in ORC 2307.71(A)(9).

104. Alternatively, Sorin Defendants are suppliers of the Sorin HCD, as that term is defined by ORC 2307.71(A)(15) and ORC 2307.78.

105. At all relevant times, the Sorin Defendants were engaged in the business, design, development, testing, promotion, manufacture, assembly, and/or sale of the Sorin HCD used in the heart surgery of Charles Yerkey at Cleveland Clinic – Main Campus on May 15, 2017.

106. The Sorin HCD was defective at the time it was designed, manufactured, assembled, and sold by the Sorin Defendants in that its defective design prevented it from being reliably and consistently cleaned, disinfected, and maintained based on the expected and reasonably foreseeable use of the Sorin HCD with its accompanying instructions, thus rendering the Sorin HCD unsafe for use by the defendant hospital for the use for which it was intended, namely the heart surgery of Charles Yerkey, the ultimate user, on May 15, 2017.

107. The Sorin HCD used by the Cleveland Clinic Defendants for the heart surgery of Charles Yerkey, on May 15, 2017, was expected to reach, and did reach, the intended consumer, Cleveland Clinic Defendants, without substantial relevant change in the condition in which it was sold by the Sorin Defendants.

108. At the time the Sorin HCD left the possession and control of the Sorin Defendants it was in a defective condition, unreasonably dangerous to Charles Yerkey, and others, in that it was contaminated with a highly virulent and deadly strain of ***m. chimaera*** during production and shipped to The Cleveland Clinic preloaded with the bacterium, thus permitting bacteria to collect, grow, and/or flourish, and subsequently be aerosolized to contaminate the surrounding area in the operating room suite during heart surgery.

109. At all relevant times, Sorin Defendants knew, or should have known, that the manufacturing defects in its Sorin HCD allowed bacterial colonization to which patients like Charles Yerkey would be, and were in fact, exposed to during heart surgery, thus posing a significant risk of bodily injury.

110. At all relevant times, the Sorin Defendants intended its Sorin HCD to be used during heart surgery cases, and knew or should have known that it would have been used in patients like Charles Yerkey, who underwent heart surgery at the Cleveland Clinic – Main Campus.

111. At all relevant times, the use of the Sorin HCD during heart surgery cases, such as in patients like Charles Yerkey, was reasonably foreseeable to the Sorin Defendants as its Sorin HCD was used in the manner for which it was intended by the Cleveland Clinic Defendants who purchased and used the Sorin HCD for the ultimate consumer, Charles Yerkey.

112. At all relevant times, Charles Yerkey could not have, by the exercise of reasonable care, discovered the manufacturing and design defects and risks as noted herein, nor could he have been expected to perceive the danger, and thus the unreasonably dangerous and hazardous condition of the Sorin HCD was unknowable to Charles Yerkey.

113. At all relevant times, the Sorin HCD used during the heart surgery of Charles Yerkey at Cleveland Clinic – Main Campus on May 15, 2017, was defectively manufactured, rendering it defective and unreasonably dangerous and hazardous when it left the possession of the Sorin Defendants.

114. At all relevant times, the Sorin HCD designed, manufactured, marketed, sold,

and/or placed in the interstate stream of commerce in the United States by the Sorin Defendants was inherently and unreasonably dangerous and defective, and was unfit and unsafe for its intended and/or reasonably foreseeable uses, and did not meet and/or perform to the expectations of consumers like Charles Yerkey, and his health care providers, including the Cleveland Clinic Defendants.

115. At all relevant times, Charles Yerkey was the ultimate consumer of the defective Sorin HCD used during his heart surgery at the Cleveland Clinic – Main Campus on May 15, 2017.

116. At all relevant times, Charles Yerkey had the reasonable expectation that the Sorin HCD would not be unreasonably dangerous and defective and would increase his risk of contracting a life-threatening NTM infection.

117. At all relevant times, the design defect of the Sorin HCD created a potentially catastrophic and/or life-threatening risk to patients like Charles Yerkey that far outweighed its utility and far outweighed the cost of designing, manufacturing, and producing an alternate design that was not defective.

118. The use of the Sorin HCD was the factual cause of the injuries and damages sustained by Charles Yerkey.

119. As a direct and proximate result of the use of the defective Sorin HCD, Charles Yerkey was catastrophically injured and sustained severe pain, suffering, disability and also incurred expenses for medical care and treatment.

120. By reason of its designing, manufacturing, assembling, and distributing the Sorin HCD in a defective and unreasonably dangerous condition, the Sorin Defendants are

strictly liable to Plaintiffs for Charles Yerkey's injuries and damages and Melody Yerkey's loss of consortium.

COUNT III
OHIO PRODUCTS LIABILITY CLAIM ORC 2307.76 STRICT LIABILITY FAILURE TO WARN

Plaintiffs v. Sorin Defendants

121. The preceding paragraphs are incorporated by reference as though fully set forth herein.

122. Sorin Defendants are the manufacturer of the Sorin HCD, as that term is defined in ORC 2307.71(A)(9).

123. Alternatively, Sorin Defendants are suppliers of the Sorin HCD, as that term is defined by ORC 2307.71(A)(15) and ORC 2307.78.

124. At the time the Sorin HCD left the possession and control of the Sorin Defendants, it was in a defective condition and unreasonably dangerous in that it contained inadequate warnings and/or instructions to alert consumers, including the Cleveland Clinic Defendants and the ultimate consumer, Charles Yerkey, of the dangerous risks and propensity to cause injury due to its defective design, subjecting Charles Yerkey to risks that exceeded the benefits of the product and risks that exceeded the expectations of any consumer, including, but not limited to, the risks of life-threatening NTM infections.

125. The Sorin Defendants failed to properly and adequately warn and instruct consumers such as Charles Yerkey, and specifically his treating physicians and health care providers, the Cleveland Clinic Defendants, as to the safest and most effective methods of using, maintaining and/or cleaning the defective Sorin HCD.

126. The Sorin Defendants failed to properly and adequately warn and instruct consumers such as Charles Yerkey, and specifically his treating physicians and health care providers, the Cleveland Clinic Defendants, that the defective design of its Sorin HCD prevented the adequate cleaning and disinfection that would prevent life-threatening infections from NTM.

127. Had the Sorin Defendants provided adequate warning and/or instructions regarding the defective design of their Sorin HCD, Charles Yerkey would not have consented to the use of the Sorin HCD.

128. The Sorin Defendants misrepresented the safety, risks, and benefits of their Sorin HCD to Charles Yerkey and his healthcare providers, Cleveland Clinic Defendants, while understating the risks and exaggerating the benefits to advance their own financial interests.

129. The failure of the Sorin Defendants to sufficiently warn the Cleveland Clinic Defendants and ultimately Charles Yerkey, was a factual cause of, and/or a substantial factor in causing, the injuries to Charles Yerkey.

COUNT IV
OHIO PRODUCTS LIABILITY CLAIM ORC 2307.78 SUPPLIER LIABILITY

(Alternative Pleading Pursuant to Ohio R. Civ. P. 8(A))

Plaintiffs v. Sorin Defendants

130. The preceding paragraphs are incorporated by reference as though fully set forth herein.

131. Sorin Defendants are suppliers of the Sorin HCD, as that term is defined by

ORC 2307.71(A)(15) and ORC 2307.78.

132. The Sorin HCD is a product, as that term is defined by ORC 2307.71(A)(12).

133. Pursuant to ORC 2307.78, the Sorin Defendants, individually and by and through their actual, authorized, and/or apparent agents, servants, and/or employees, were negligent and reckless by reason of its designing, supplying, assembling, and distributing the Sorin HCD used by the Cleveland Clinic Defendants during the heart surgery performed on Charles Yerkey on May 15, 2017, in one or more of the following particular respects:

a. Failure to manufacture, supply, design, and/or produce a Sorin HCD that was not "adulterated" within the meaning of section 501(h) of the Act in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 280;

b. Failure to establish and maintain procedures for the identification, documentation, validation, or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i);

c. Failure to validate a process, with a high degree of assurance and approved according to established procedures, whose results can be fully verified by subsequent inspection and test, as required by 21 CFA 820.75(a);

d. Failure to adequately develop, implement, and maintain written Medical Device Reporting ["MRD"] procedures as required by 21 CFR 803.17;

e. Failure to submit to the FDA an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g);

f. Failure to notify the FDA of the intent to introduce the device into commercial distribution as required by section 510(k) of the Act, 21 U.S.C. § 360(k), resulting in misbranding of the Heater Cooler

System 3T as defined by section 520(0) of the Act, 21 U.S.C.§ 352(0);

g. Failure to submit to the FDA a new 510(k), to assure that the appropriate testing and validation of the cleaning/disinfecting protocols had taken place, following significant labeling changes that can affect the safety or effectiveness of the device, specifically, distributing the Sorin HCD with modified Instructions for Use ["IFU"] (Versions 013 and 014) with respect to the operating, maintaining, cleaning, and disinfecting of the device, including adding more instruction details, changes to the cleaning/disinfecting process (e.g. chemicals used and amounts used), and expansion of the process to include the entire circuit instead of only the tanks;

h. Failure or refusal to furnish material or information, with respect to the device in question, to the FDA as required by or under section 519 of the Act, 21 U.S.C. § 3601, and 21 CFR Part 806-Medical Devices; Reports of Corrections and Removals, resulting in "misbranding" of the Sorin HCD device as defined in section 502(t)(2) of the Act, 21 U.S.C. §352(t)(2);

i. Failure to submit to the FDA a written report, as required by 21 CFR 806.10, of any correction or removal of advice initiated to remedy a violation of the Act caused by the device which may present a risk to health;

j. Failure to adequately, appropriately, properly, reasonably, and timely address the problems with their Sorin HCD after learning of an unusual cluster of non-tuberculous mycobacterium seen in patients, post- cardiothoracic surgery;

k. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning of recent reports from Europe indicating that aerosolization of this NTM bacteria being emitted from the Sorin heater cooler device;

l. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning of concerns on the maintenance of this machine;

m. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning of inconsistencies between the manufacturer instructions and the user manual, field safety notice, FAQ, "quick start" guide, and instructional video;

n. Failure to adequately, appropriately, properly, reasonably, and timely consistently distribute the method of updating disinfection requirements for the Sorin HCD;

o. Failure to adequately, appropriately, properly, reasonably, and timely train their servants, employees and/or agents regarding the method of cleaning, maintaining, and/or disinfecting the Sorin HCD such that their sales representative's verbal info is consistent with the written recommendations;

p. Failure to adequately, appropriately, properly, reasonably, and timely train their servants, employees and/or agents regarding the method of cleaning, maintaining, and/or disinfecting the Sorin HCD such that company's representative sent to place a new machine in production would follow the manufacturer's established guidelines for disinfection;

q. Failure to adequately, appropriately, properly, reasonably, and timely develop and provide to the Cleveland Clinic Defendants and their servants, employees and/or agents, including the treating healthcare providers of Charles Yerkey, disinfection procedure changes that will actually mitigate any potential biofilm growth;

r. Failure to adequately, appropriately, properly, reasonably, and timely develop and provide to the Cleveland Clinic Defendants and their servants, employees and/or agents, including the treating healthcare providers of Charles Yerkey, documentation or studies that disinfection procedure changes actually mitigate any potential biofilm growth;

s. Failure to adequately, appropriately, properly, reasonably, and timely develop and provide to the Cleveland Clinic Defendants and their servants, employees and/or agents, including the treating healthcare providers of Charles Yerkey, steps for meeting the new recommended disinfection protocols that are not confusing and complex;

t. Failure to adequately, appropriately, properly, reasonably, and timely design their Sorin HCD so as to make it less susceptible to cause life- threatening infections with NTM;

u. Failure to adequately, appropriately, properly, reasonably and, timely design their Sorin HCD so as to prevent life-threatening infections with NTM;

v. Failure to adequately, appropriately, properly, reasonably, and timely test the Sorin HCD to determine if the distributed instructions for cleaning and disinfecting actually prevented life

threatening infections with NTM;

w. Failure to adequately, appropriately, properly, reasonably, and timely test the Sorin HCD to determine if the design increased the risk, compared to alternate designs, of life-threatening infections with NTM;

x. Failure to adequately, appropriately, properly, reasonably, and timely eliminate, rectify, and/or warn of known risks and dangers of life- threatening infections with NTM associated with their Sorin HCD;

y. Failure to adequately, appropriately, properly, reasonably, and timely recall, modify, retrofit, and/or re-design their defective Sorin HCD;

z. Failure to adequately, appropriately, properly, reasonably, and timely remove their defectively designed Sorin HCD from the stream of commerce;

aa. Failure to adequately, appropriately, properly, reasonably, and timely recommend users of their defective Sorin HCD to stop using their defective Sorin HCD product;

bb. Failure to adequately, appropriately, properly, reasonably, and timely design a HCD that did not create a no-flow and/or low-flow area or areas, and/or blind spots, that made the Sorin HCD more difficult and/or impossible to adequately clean, disinfect, and/or maintain, thus increasing the risk of contamination with NTM and increasing the risk of infecting the patient who is in the operating room undergoing open heart surgery with an NTM infection;

cc. Failure to adequately, appropriately, properly, reasonably, and timely design a HCD that was easier to maintain, clean, and/or disinfect;

dd. Failure to adequately, appropriately, properly, reasonably, and timely monitor and test the production line in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

ee. Failure to adequately, appropriately, properly, reasonably, and timely monitor and test the water supply used in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

ff. Failure to formulate, adopt, and/or enforce the appropriate rules, guidelines, policies, and/or protocols, and to properly oversee and supervise all persons in their corporation who are responsible to

ensure that these protocols are followed, to prevent the failure to adequately, appropriately, properly, reasonably, and timely monitor and test the production line in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

gg. Failure to formulate, adopt, and/or enforce the appropriate rules, guidelines, policies, and/or protocols, and to properly oversee and supervise all persons in their corporation who are responsible to ensure that these protocols are followed, to prevent the failure to adequately, appropriately, properly, reasonably, and timely monitor and test the water supply used in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

hh. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning, as early as 2011 of reports from Europe indicating that aerosolization of NTM bacteria being emitted from the Sorin heater cooler device was causing serious life-threatening infections in patients undergoing cardiac surgery, and in 2011 when the FDA inspected their manufacturing facility in Germany and issued an Establishment Inspection Report noted multiple quality violations;

ii. Failure to adequately, appropriately, properly, reasonably, and timely remove from the stream of commerce, and/or recommend that hospitals stop using, their defectively designed Sorin HCD when they knew, as early as September, 2013, that the water supply for the production line in their Sorin HCD manufacturing facility in Germany was contaminated with NTM;

jj. Failure to adequately, appropriately, properly, reasonably, and timely warn hospitals who had purchased their Sorin HCD of the design problems with their Sorin HCD after learning, as early as 2011 of reports from Europe indicating that aerosolization of NTM bacteria being emitted from the Sorin heater cooler device was causing serious life-threatening infections in patients undergoing cardiac surgery, and in 2011 when the FDA inspected their manufacturing facility in Germany and issued an Establishment Inspection Report noted multiple quality violations, and when they knew, as early as September, 2013, that the water supply for the production line in their Sorin HCD manufacturing facility in Germany was contaminated with NTM; and,

kk. Failure to adequately, appropriately, properly, reasonably, and timely remove from the stream of commerce, and/or recommend that hospitals stop using, their defectively designed Sorin HCD when they knew, as early as September, 2013, that the water supply for the production line in their Sorin HCD manufacturing facility in

Germany was contaminated with NTM.

134. As a direct and proximate result of the actual malice, conscious disregard, tortious, willful, and negligent conduct of the Sorin Defendants, Charles Yerkey was catastrophically injured and sustained severe pain, suffering, disability, impairment and also incurred expenses for medical care and treatment.

135. Plaintiffs claim all damages recoverable under the law, including compensatory and punitive damages.

COUNT V

NEGLIGENCE

Plaintiffs v. Sorin Defendants

136. The preceding paragraphs are incorporated by reference as though fully set forth herein.

137. The Sorin Defendants individually and by and through their actual, authorized, and/or apparent agents, servants, and/or employees, were negligent and reckless by reason of its designing, manufacturing, assembling, and distributing the Sorin HCD used by the Cleveland Clinic Defendants during the heart surgery performed on Charles Yerkey on May 15, 2017, in one or more of the following particular respects:

a. Using contaminated tap water during production and thus introducing a deadly strain of *m. chimaera* into the water tanks of the Sorin HCD prior to shipment to customers;

b. Failing to disinfect the water tanks of the Sorin HCD during final production, as Sorin promised the FDA it would in order to get 510k clearance to sell the devices in the United States;

c. Failure to adequately, appropriately, properly, reasonably, and timely design, manufacture, assemble and distribute their Sorin HCD so as to make it less susceptible for life-threatening mycobacteria to contaminating and/or polluting the surgical field environment at the

Cleveland Clinic – Main Campus during Charles Yerkey's heart surgery; and,

d. Failure to adequately, appropriately, properly, reasonably and, timely design, manufacture, assemble and distribute their Sorin HCD so as to prevent life-threatening mycobacteria from contaminating and/or polluting the surgical field environment at the Cleveland Clinic – Main Campus during Charles Yerkey's heart surgery.

138. The Sorin Defendants undertook and/or assumed a duty of care to Charles Yerkey and to avoid harm to him, which duty was breached by defendants.

139. Charles Yerkey relied on the duty of care owed by the Sorin Defendants.

140. The Sorin Defendants breached its duty of care to Charles Yerkey and his healthcare providers, including the Cleveland Clinic Defendants, through its wanton, outrageous, reckless and negligent polluting and/or contaminating of the surgical field environment at Cleveland Clinic – Main Campus by its Sorin HCD that was used in the heart surgery of Charles Yerkey.

141. Despite the fact that the Sorin Defendants knew, or should have known, as early as 2011 during the FDA inspection that the defective design of the Sorin HCD caused the surgical environment fields at hospitals to be contaminated and/or polluted with life threatening mycobacteria, the Sorin Defendants continued with reckless indifference to public and consumer safety to promote, manufacture, assemble, sell, and distribute their Sorin HCD.

142. For a significant period of time before the open heart surgery of Charles Yerkey, in January of 2014, the Sorin Defendants knew, or should have known, that their Sorin HCD design was defective and that their production line water supply was contaminated with NTM, and, as a result, their Sorin HCD was contaminating and/or polluting the surgical environment field with mycobacteria causing life-threatening infections with NTM in patients

in whom the Sorin HCD was used during open heart surgery.

143. The Sorin Defendants, while actually and subjectively aware of the significant increased risk involved, nevertheless proceeded with actual malice and conscious disregard to the rights, safety, and welfare of others, and/or proceeded with aggravated and egregious fraud in providing material representations that were false and known to be false and/or made as positive assertions of safety, all with conscious reckless disregard to the truth, with the intent that these false representations would result in consumers, like the Cleveland Clinic Defendants, and ultimate consumers, like Charles Yerkey, to continue to purchase and/or use their defective Sorin HCD that was contaminating and/or polluting the surgical environment field with mycobacteria causing life- threatening infections with NTM in patients in whom the Sorin HCD was used during open heart surgery.

144. Despite the possession of the knowledge and information described herein, the Sorin Defendants failed to modify, amend, and/or alter their advertising, promotional literature, labeling, warning, and/or instructions to adequately disclose to treating physicians and health care providers of Charles Yerkey, including the Cleveland Clinic Defendants and their agents, and the ultimate consumer, Charles Yerkey, that the defective Sorin HCD was contaminating and/or polluting the surgical environment field with mycobacteria causing life-threatening infections with NTM in patients in whom the Sorin HCD was used during open heart surgery.

145. The failure of the Sorin Defendants to re-design and/or re-label and/or amend its advertising, promotional literature, instructions, and/or warnings, was a conscious disregard to the health and well-being of consumers, such as the Cleveland Clinic Defendants, as this conduct was intended to conceal the adverse information known by the Sorin Defendants

from the consumer, treating physicians and healthcare providers of Charles Yerkey, including the Cleveland Clinic Defendants and their agents.

146. The actual malice, conscious disregard and aggravated and egregious fraud, tortious and negligent conduct of the Sorin Defendants increased the risk of harm of, was a substantial factor in causing, and/or was a factual cause of the injuries and damages suffered by Charles Yerkey, as set forth more fully above.

147. The Sorin Defendants acted with actual malice and conscious disregard of the increased risk of harm that was substantially greater than that which was necessary to make their conduct necessary.

148. As a direct and proximate result of the actual malice, conscious disregard, aggravated and egregious fraud, tortious and negligent conduct of the Sorin Defendants in its Sorin HCD contaminating and/or polluting the surgical environment field with mycobacteria causing life-threatening infections with NTM in patients in whom the Sorin HCD was used during open heart surgery, as set forth herein, Charles Yerkey was catastrophically injured and sustained severe pain, suffering, disability, impairment and also incurred expenses for medical care and treatment.

149. The conduct of the Sorin Defendants described herein, was aggravated by the actual malice and conscious disregard to the health and well-being of consumers, including Charles Yerkey, for which the law allows, and plaintiffs will seek, the imposition of punitive damages.

COUNT VI
BREACH OF IMPLIED WARRANTY

Plaintiffs v. Sorin Defendants

150. The preceding paragraphs are incorporated by reference as though fully set forth herein.

151. At all relevant times, the Sorin Defendants manufactured, assembled, marketed, advertised, promoted, sold, distributed, and/or placed into interstate commerce their defective Sorin HCD, including the Sorin HCD used by the Cleveland Clinic Defendants during the heart surgery of Charles Yerkey.

152. At all relevant times, the Sorin Defendants intended their Sorin HCD to be used during heart surgery and it was used for the heart surgery of Charles Yerkey.

153. At all material times hereto, the Sorin Defendants breached implied warranties with respect to their Sorin HCD, including implied warranties that their Sorin HCD was of merchantable quality, and that their Sorin HCD had been adequately and appropriately tested, and was fit for its intended use during heart surgery.

154. The treating physicians and healthcare providers of Charles Yerkey including the Cleveland Clinic Defendants and their servants, employees and/or agents, and the ultimate consumer Charles Yerkey, in reliance on these warranties, used the defective Sorin HCD during Charles Yerkey's heart surgery.

155. At the time of making such implied warranties, the Sorin Defendants knew, or should have known, that their Sorin HCD did not conform to these implied warranties because it was not safe due the defective design that increased the risk of life-threatening NTM infections, thus making the Sorin HCD unreasonably dangerous for its intended use.

156. The breach of these implied warranties made by the Sorin Defendants to the treating physicians and healthcare providers of Charles Yerkey including the Cleveland Clinic Defendants and their servants, employees and/or agents, and the ultimate consumer Charles Yerkey, was a substantial factor in, and/or a factual cause of, the injuries to Charles Yerkey.

157. As a direct and proximate result of the actual malice, conscious disregard, tortious, willful, and negligent conduct of the Sorin Defendants, Charles Yerkey was catastrophically injured and sustained severe pain, suffering, disability, impairment and also incurred expenses for medical care and treatment.

158. Plaintiffs claim all damages recoverable under the law, including compensatory and punitive damages.

COUNT VII

NEGLIGENCE

Plaintiffs v. Cleveland Clinic Defendants

159. The preceding paragraphs are incorporated by reference as though fully set forth herein.

160. The Cleveland Clinic Defendants negligently used the Sorin HCD during Charles Yerkey's May 15, 2017 heart surgery, despite knowing or having reason to know that it may have been contaminated with NTM.

161. The Cleveland Clinic Defendants failed to take mitigating action to reduce the risk of infection, including using sterile water in the machine, removing biofilm, preventing the aerosolizing of mycobacterium, and/or positioning the Sorin HCD away from the surgical

field.

162. The Cleveland Clinic Defendants failed to properly clean, maintain and disinfect the Sorin HCD.

163. The Cleveland Clinic Defendants undertook and/or assumed a duty to use clean and contaminant-free medical equipment, including the Sorin HCD with respect to Charles Yerkey's May 15, 2017 surgery and to avoid harm to him, which duty was breached by Cleveland Clinic Defendants.

164. Charles Yerkey relied on the knowledge, treatment, and skill of the Cleveland Clinic Defendants.

165. The carelessness and negligence of the Cleveland Clinic Defendants increased the risk of harm to, and was a substantial factor in causing, and/or a factual cause of, the injuries and damages suffered by Charles Yerkey.

166. As a direct and proximate result of the negligent conduct of the Cleveland Clinic Defendants, Charles Yerkey was catastrophically injured and sustained severe pain, suffering, disability, impairment and also incurred expenses for medical care and treatment.

167. Plaintiffs claim all damages recoverable under the law, including compensatory damages.

COUNT VIII
LOSS OF CONSORTIUM

Plaintiffs v. All Defendants

168. The preceding paragraphs are incorporated by reference as though fully set forth herein.

169. Plaintiff, Melody Yerkey, was at all times relevant married to Plaintiff, Charles Yerkey, and as a result of the injuries and damages Charles Yerkey sustained, as alleged more fully above, Melody Yerkey lost the society, comfort, care and companionship of her husband, Charles Yerkey.

170. As a direct and proximate result of the carelessness, negligence, actual malice, conscious disregard and strict liability of the Defendants herein which caused the aforementioned injuries and losses to Plaintiff, Charles Yerkey, Plaintiff, Melody Yerkey, has been, and will in the future continue to be deprived of services, society and conjugal fellowship of her husband.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, Charles Yerkey and Melody Yerkey demand damages against all Defendants, including compensatory and punitive damages (punitive damages against the Sorin Defendants only), jointly and severally, in an amount in excess of $25,000.00, plus interest, costs, attorney's fees and all other relief that this Court deem just and necessary.

JURY DEMAND

A trial by jury is hereby requested in the maximum number allowed by law at the time of the trial of the within action.

Respectfully submitted,

/s/ William Hawal
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Attorneys for Plaintiffs

STATE OF OHIO }
} SS
COUNTY OF CUYAHOGA }

AFFIDAVIT OF MERIT
OF Matthew Warhoover

NOW COMES AFFIANT, Matthew Warhoover, having first been duly sworn, states as follows:

1. I have personal knowledge of the facts contained within this Affidavit.

2. I am a licensed perfusionist and hold the position of chief of perfusion at Vanderbilt University Medical Center. I am certified with the American Board of Cardiovascular Perfusion.

3. I have considered the materials related to Charles Yerkey and his cardiac surgery at Cleveland Clinic in May of 2017, utilizing the Sorin 3T machine. I am professionally familiar with the Sorin 3T machine and its use and maintenance stemming both from my consideration of this case and from having provided expert analysis and opinion in other Sorin 3T contamination cases.

4. I am familiar with the appropriate standards associated with maintaining and operating the Sorin 3T machines.

5. Based upon my review of the materials it is my professional opinion that Cleveland Clinic and its' employees deviated from the appropriate and acceptable standard, which deviations directly resulted in injury and damages to Charles Yerkey.

FURTHER AFFIANT SAYETH NAUGHT.

DocuSigned by:
1755437A03784B8

Subscribed hereto in my presence this 17 day of May, 2022.

Notary Public

Judibeth Contreras Rosado
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES April 1st, 2025